Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-20. (Canceled)

21. (Currently Amended) An autoclavable composition of an aqueous injectable, terminally steam sterilized suspension in a vial sealed under nitrogen atmosphere, said suspension containing particles of a water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of a size of 10 μm or greater ~~size~~ and not more than 300 particles of a size of 25 μm or greater ~~size~~, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount ~~safe for parenteral administration~~ of a ~~pharmaceutically acceptable,~~ water soluble polyhydroxy thermoprotecting agent selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol and mixtures thereof, wherein the ratio of said active substance to said phospholipid surface modifier is from about 3:1 to about 5:1 and the amount of said phospholipid surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier, said composition [is] being devoid of surfactant additives which coagulate on steam sterilization, and ~~said~~ further wherein the volume weighted mean particle size of said particles is not increased more than two-fold during and after terminal steam sterilization. ~~, and the ratio of the amount of the active substance and the thermoprotecting agent selected to provide particle size stability during and after terminal steam sterilization~~.

22. (Currently Amended) An autoclavable composition of an injectable, non-flocculating, aqueous, terminally steam sterilized suspension under nitrogen in a sealed vial, said suspension containing particles of a water insoluble or poorly soluble drug substance with a volume weighted mean particle size of up to 3 μm, ~~with not more than 3000 particles of 10 μm or greater size and not more than 300 particles of 25 3 μm or greater size~~ said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount ~~safe for parenteral administration~~ of a ~~pharmaceutically acceptable,~~ water soluble polyhydroxy

thermoprotecting agent, wherein (i) the ratio of said drug substance to said surface modifier is about 3:1 to about 5:1, (ii) the amount of said surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, and (iii) said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier and is devoid of surfactant additives which coagulate on steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent is selected to provide particle size stability during and after terminal steam sterilization.

23. (Currently Amended) The composition [of] according to claim 21 or claim 22, wherein the suspension also includes a nonsurfactant additive to adjust osmotic pressure.

24. (Currently Amended) The composition [of] according to claim 21 or claim 22, wherein the suspension ~~can be~~ is diluted with water for parenteral administration.

25. (Currently Amended) The composition [of] according to claim 22, wherein the polyhydroxy compound is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol[,] and mixtures thereof.

26. (Currently Amended) The composition [of] according to claim 21 or claim 22, wherein the phospholipid surface modifier is selected from the group consisting of natural phospholipids and synthetic phospholipids.

27. (Currently Amended) The composition [of] according to claim 26, wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

28. (Currently Amended) The composition [of] according to claim 22, wherein the suspension ~~also contains~~ further comprises a pharmaceutical excipient for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble drug substance.

29. (Currently Amended) The composition [of] according to claim 21[.], wherein the active substance is an antifungal agent.

30. (Currently Amended) The composition [of] according to claim 29, wherein the antifungal agent is itraconazole.

31. (Currently Amended) The composition [of] according to claim 21, wherein the active substance is an immunosuppressive agent.

32. (Currently Amended) The composition [of] according to claim 21, wherein the active substance is a sterol.

33. (Currently Amended) The composition [of] according to claim 32, wherein the sterol is alfaxalone.

34. (Currently Amended) A lyophilized or spray dried powder prepared from the composition [of] according to claim 22.

35. (Previously Presented) The composition according to claim 22, wherein the water-insoluble or poorly water soluble drug substance is suitable for either immediate release or sustained release delivery of said drug substance by parenteral administration.

36. (Currently Amended) The composition [of] according to claim 35, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

37. (Currently Amended) The composition [of] according to claim 31, wherein the immunosuppressive agent is a cyclosporin.

38. (Currently Amended) An aqueous suspension comprising (i) particles of a water insoluble or poorly soluble biologically active substance, (ii) from about 0.2 % w/w to about 5 % w/w of one or more phospholipid surface modifiers, and (iii) a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance, said particles comprising ~~with~~ a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of a size of 10 μm or greater ~~size~~ and not more than 300 particles of a size of 25 μm or greater ~~size~~, wherein the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent ~~being~~ is

selected so as to provide particle size stability during and after terminal steam sterilization, and wherein the volume weighted mean particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, and the suspension is devoid of surfactants which coagulate on steam sterilization.

39. (Canceled)

40. (Currently Amended) The suspension [of] according to claim 38, wherein the pH of the suspension before terminal steam sterilization is from about 5 to about 9.

41. (Currently Amended) The suspension [of] according to claim 38, ~~which also includes~~ further comprising a non-surfactant additive to adjust osmotic pressure of the suspension.

42. (Currently Amended) The suspension [of] according to claim 38, ~~which also includes~~ further comprising an amount of a non-surfactant additive such that, on diluting the suspension with a pharmaceutically acceptable diluent suitable for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, a suitable osmotic pressure of the diluted suspension results.

43. (Currently Amended) The suspension [of] according to claim 38, wherein the thermoprotecting agent is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

44. (Currently Amended) The suspension [of] according to claim 38, wherein the one or more phospholipid surface modifiers are natural phospholipids or synthetic phospholipids.

45. (Currently Amended) The suspension [of] according to claim 44[.], wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

46. (Currently Amended) The suspension [of] according to claim 38, wherein the amount of the surface modifier provides a biologically active substance to surface modifier ratio of 3:1 to 5:1.

47. (Canceled)

48. (Currently Amended) The suspension [of] according to claim 38, ~~wherein the composition also contains~~ further comprising a pharmaceutical excipient for ~~opthalmic~~ ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble ~~biological~~ biologically active substance.

49. (Currently Amended) The suspension [of] according to claim 38, wherein the active substance is an antifungal agent.

50. (Currently Amended) The suspension [of] according to claim 49, wherein the antifungal agent is itraconazole.

51. (Currently Amended) The suspension [of] according to claim 38, wherein the active substance is an immunosuppressive ~~immuno-supressive~~ drug.

52. (Currently Amended) The suspension [of] according to claim 51, wherein the immunosuppressive ~~immuno-supressive~~ drug is a cyclosporin.

53. (Currently Amended) The suspension [of] according to claim 38, wherein the active substance is a sterol.

54. (Currently Amended) The suspension [of] according to claim 53, wherein the sterol is alfaxalone.

55. (Canceled)

56. (Currently Amended) The suspension [of] according to claim 38, wherein the water-insoluble or poorly water-soluble biologically active substance is at a pharmaceutically acceptable concentration for either immediate release or sustained release delivery of the active substance by parenteral administration.

57. (Currently Amended) The suspension [of] according to claim 56, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

58.-62. (Canceled)

63. (New) The aqueous suspension according to claim 38, further wherein the suspension is substantially devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization.